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APPLICATION NO. | FILING DATE | NAME OF APPLICANT | ATTORNEY DOCKET NO.

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EXAMINER

187

ART UNIT | PAPER NUMBER

12/19/90

14

DATE MAILED:

☒ This application has been examined ☒ Responsive to communication filed on 7/3/90 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 12-32 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-11 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 12-32 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev.9-89)

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 180, Art Unit 187.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claim 12 lacks enablement as to how to practice the preparation of probes claimed therein: There is a lack of enablement for determining what probes (size and sequence) can be used to practice the specific affinities claimed. It would require undue experimentation to try probes with human digests of DNA to find which ones out of the multitude possible would have the desired specificity.

Claim 14 cites the detection of amplification rearrangement or over-expression. Since the detection of single copy genes by hybridization is possible, the differentiation of this from the amplified or over-expressed gene is unclear and lacks enablement.

Claims 12-32 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 12-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12, for example, cites a probe having affinity for "at least a part of a gene...". It is unclear what probe is being claimed since the affinity is for a "part" of the gene. Thus, the "part" could be a 4 base "AAAA" stretch and the probe would be "TTTT". Is this what is being claimed? Does the probe have to have the entire sequence cited in claim 12 within its length? What are the metes and bounds of the phrase "nucleic acid derivative thereof"? Is this labeled probe? Is it a sequence with base changes? Additionally, which is the 5'-end and which is the 3'-end of the cited sequence (in all the instant claims with sequences)? What is being claimed in claim 12?

What are the metes and bounds of the "instructions" of claim 13? It is unclear how to practice the kit contents of claim 13 since multiple "specific" probes are cited as kit contents. Why would one need more than one "specific" probe and how would one

select these multiple probes?

Claim 14 cites claim 5 in its last line. Claim 5 has been canceled. It is improper for a claim to depend from a canceled claim. Also, the practice of part (b) of claim 14 is to a non-elected invention and therefore also improper.

It is unclear how to practice the determination of protein in claim 15 within the elected restriction group. It is also unclear what is being claimed in claim 15 by "defined amounts". As worded, claim 15 reads on all cells having zero v-erbB-related DNA or RNA since zero is an easily defined amount. Clarification of what is being claimed is requested.

Claim 16 is unclear since the first line cites an "amino acid seequence" whereas the cited sequence is nucleic acid. Note spelling error in the word "seequence".
What are the metes and bounds of "a fragment thereof" used in claim 16? Can this be a single nucleotide as the claim language permits? Note that the word "complimentary" appears to be misspelled in claim 16.

What are the metes and bounds of "a carrier" of claims 17 and 21?

Claim 21 has a confusing and unclear wording in the phrase "comprising a at least".

Claims 31 and 32 are rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

In order to practice claim 26 the limitations of claims 31

and 32 must inherently be present.

> 35 U.S.C. § 101 reads as follows:
> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 12-32 are rejected under 35 U.S.C. § 101 because the utility of detecting cancer is not demonstrated for the claimed fragments. Possibly the entire cited sequence may have the stated utility but the critical probes having the utility if they are over a certain size and sequence is not demonstrated.

Any inquiry concerning this communication should be directed to Ardin Marschel, Ph.D., at telephone number: (703) 308-0196.

AM

A. MARSCHEL:am

December 13, 1990

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
ART UNIT 187